Mycobacterium tuberculosis complex nucleic acid amplification test (MTBC NAAT)

Test Description	Nucleic acid assay for the direct detection *of Mycobacteria tuberculosis* complex DNA in pulmonary specimens. Also, to detect mutation of the rpoB gene as an indicator of rifampin resistance.
Test Use	To aid in the rapid identification of primary tuberculosis disease and rifampin resistance in patients that are acid fast smear positive.
Test Department	Mycobacteriology Laboratory Phone: (860) 920-6649 FAX: (860) 920-6721
Methodology	Semi-quantitative nested real-time polymerase chain reaction
Availability	Daily, Monday-Friday
Specimen Requirements	A minimum of 3 mL (5-10 mL preferred) raw, unprocessed sputum, bronchial lavage, or bronchial washings from patients who have never received anti-tuberculous therapy, received < 7 days of therapy at the time of specimen collection, or no therapy within the last year.
Collection Kit/Container	To obtain collection kit, refer to Collection Kit Ordering Information
Collection Instructions	Collect specimen into sterile container
Specimen Handling & Transport	Store specimen at 2-8° C. Transport to the laboratory as soon as possible with an ice pack coolant (preferred) or at ambient temperature. Avoid temperature extremes. Specimens must be received within 10 days of collection.
Unacceptable Conditions	Unlabeled specimen Specimens that have leaked or containers that have broken in transit Extra-pulmonary specimens Processed pulmonary specimens
Requisition Form	Clinical test requisition (select **AFB Clinical Specimen**) Nucleic Acid Amplification Test Requisition may be found at the Dr. Katherine A. Kelley State Public Health Laboratory webpage located at, www.ct.gov/dph/cwp/view.asp?a=3122&q=396860
Required Information	Name and address of submitter (and/or Horizon profile #). Patient name or identifier, date of birth, town of residence (city, state, zip). Specimen type or source of collection, test requested. Please ensure patient name on requisition matches that on the specimen.
Limitations	• A positive test result does not indicate the presence of viable organisms. • A positive result is presumptive evidence for the presence of *Mycobacterium tuberculosis* complex and/or rifampin resistance. • This test should NOT be ordered when clinical suspicion is low, to determine bacteriologic cure, or to monitor response to anti-tuberculosis drug therapy.
Additional Comments	• Acid fast microscopy and culture for the isolation / identification of acid-fast bacteria is also performed on all samples submitted for MTBC NAAT. • This test is automatically done on the first patient specimen submitted for AFB smear and culture that is found to be acid fast smear positive. Testing of AFB

	smear negative specimens is only performed upon request.

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